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EXAMINER

WELLS, LAUREN Q

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 12/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/936,953

Applicant(s)

SUNAMOTO ET AL.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All   b) ☐ Some \*   c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-9 are pending. The Preliminary Amendment filed 9/17/01, amended claims 3-9.

#### ***Specification***

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) Claim 1 is vague and indefinite, as it is confusing. First, it is not clear what is being claimed, as there are two transitional terms, "containing" and "comprising", and it is not clear what language encompasses the preamble. Is a product containing a polysaccharide-sterol derivative being claimed, or is a composition comprising cosmetic components and a polysaccharide-sterol derivative being claimed?

(ii) The term "derivative" in claims 1 (lines 2, 4), 2 (line 2), 3 (lines 3), 6 (lines 2-3), 7 (line 3) is vague and indefinite, as it is not clear what compounds are encompassed by this

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phrase. The specification does not definitely define this phrase and one of ordinary skill in the art would not be apprised of all the possible chemical compounds encompassed by this term, as there are an infinite number of combinations of sterols, sterol derivatives, polysaccharides, and polysaccharide derivatives.

(iii) The phrase “steryl group” in claims 2, 3 (line 9), 4 (line 3), 5 (line 3) is vague and indefinite, as it is not clear what chemical compounds or fragments are encompassed by this phrase. The specification does not define this phrase and one of ordinary skill in the art would not be apprised of what this phrase chemically encompasses.

(iv) The phrase “hydrocarbyl of 1-10 carbon atoms” in claim 3 (line 8) is vague and indefinite, as it is not clear what chemical compounds or fragments are encompassed by this phrase. The specification does not define this phrase and one of ordinary skill in the art would not be apprised of what this phrase chemically encompasses. Is hydrocarbyl referring to hydrocarbon?

(v) Claims 4 and 5 are vague and indefinite, as they are confusing. What does the phrase “proportion of introduction” mean? Are hydroxyl groups synonymous to steryl groups? Claim 2, recites hydroxyl groups. . .in a proportion of. . .per 100 monosaccharide units.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 10017434.

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JP '434 teaches cosmetic compositions comprising a hydroxy alkylated cyclodextrin, a cholesterol ester, clay mineral, and water. Lipsticks are disclosed as preferred forms. Thus, both Applicant and JP '434 teach make-up composition comprising hydroxyalkylated cyclodextrin and cholesterol ester (a polysaccharide-sterol derivative). See abstract.

Claims 1, 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Nabeshima et al. (JP 409095413).

Nabeshima et al. teach a preparation for external skin use comprising 0.01-10% of a cholesterol ester in a hydroxyalkylated cyclodextrin and a quaternary ammonium salt. The weight ratio of the hydroxalkylated dextrin to the cholesterol ester is 99:1 to 90:10. Thus, both Applicant and Nabeshima et al. teach a skin care composition comprising 0.01-10% of a polysaccharide-sterol derivative (cholesterol ester in a hydroxyalkylated cyclodextrin). See abstract.

Claims 1 and 8-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Shimomura et al. (JP 408026971).

Shimomura et al. teach a composition comprising an acidic polysaccharide and sterols. Lotions, creams, and milks are disclosed as cosmetic forms. Thus, both Applicant and Shimomura et al. teach skin care cosmetic compositions comprising polysaccharide-sterol derivatives (acidic polysaccharide and sterols) in the form of emulsions (lotions, creams, and milks). See abstract.

Claims 1, 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Hamano et al. (5,871,759).

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Hamano et al. teach a hydrous composition comprising 5-30% of a hydroxyalkylated cyclodextrin, 5-80% of a cholesterol ester, clay mineral, hydrophobic silica, and water.

Disclosed is a process of making a cosmetic composition comprising mixing and stirring the above composition. 0.5-30% of the hydrous compositions is part of the cosmetic product.

Lipsticks are exemplified as preferred embodiments. Thus, both Applicant and Hamano et al. teach make-up compositions comprising polysaccharide-sterol derivative (5-30% hydroxyalkylated cyclodextran, 5-50% cholesterol ester). See Col. 31, line 47-Col. 34, line 21.

Claims 1-7 and 9 rejected under 35 U.S.C. 102(b) as being anticipated by Yamaguchi et al. (EP 370810).

Yamaguchi et al. teach fatty emulsions stabilized by polysaccharide derivatives, wherein the polysaccharide is substituted by a fatty acid or cholesterol at a proportion of 0.5-5 per 100 sugar units. Exemplified is a composition comprising N-[2-

cholesteryloxy carbonylamino)ethyl] carbamoylmethylated pullan, panasate, glycerin, and water.

Exemplified is a composition comprising N-[2-

cholesteryloxy carbonylamino)ethyl] carbamoylmethylated pullan, soybean oil, glycerin, and

water. Exemplified is a composition comprising N-[2-

cholesteryloxy carbonylamino)ethyl] carbamoylmethylated pullan, fish oil, glycerin, and water.

Exemplified is a composition comprising N-[2-

cholesteryloxy carbonylamino)ethyl] carbamoylmethylated pullan, perilla oil, glycerin, and water.

Exemplified is a composition comprising N-[2-

cholesteryloxy carbonylamino)ethyl] carbamoylmethylated pullan, alpha linolenic acid, glycerin,

and water. Thus, both Applicant and Yamaguchi et al. teach emulsions comprising 0.001-50%

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pullulan-cholesterol derivatives, wherein the polysaccharide is substituted by a fatty acid or cholesterol at a proportion of 0.5-5 per 100 sugar units. See page 3, line 50-pg. 7, line 40.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamaguchi et al. in view of Backer.

Yamaguchi et al. is applied as discussed above. The reference lacks a skin care cosmetic form.

Kondo et al. teach skin care compositions comprising perilla oil. See abstract.

Force et al. teach soybean oil as providing skin softness in cosmetic compositions. See Col. 6, lines 41-46.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the composition of Yamaguchi et al. as a skin care composition because Yamaguchi et al. exemplify compositions comprising soybean oil and perilla oil and Force et al. teach that soybean oil is known to provide skin softness in skin care compositions, and Kondo et al. teach that using perilla oil in skin care compositions is known.

***Unexpected Results***

It is applicant's burden to demonstrate unexpected results over the closest prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated

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with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).

In the instant case, the data on pages 64-98 of the specification have been considered but not found persuasive because the data merely demonstrate the effectiveness of the instant composition as a moisturizer. This is seen to be an expected result based on the cited prior art. Additionally, Applicant's comparative examples are not over the closest prior art, as the closest prior art teaches polysaccharides and sterols in composition together. Furthermore, it is not known how "wet feel" measurements, "improved stretch" measurements, "lubrication feel" measurements, and "sunburn prevention" measurements, are measured and how these properties demonstrate unexpected results.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Russell S. Travers can be reached on (703)308-4603. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.




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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw  
August 15, 2002



DAMERON L. JONES  
PRIMARY EXAMINER